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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

April 15, 2002

VIA FEDERAL EXPRESS

Carolyn S. Hale, Co-Owner
Royaloff Caviar Company
2501 Wayne Road
Savannah, TN 38372

Warning Letter No. 02-NSV-20

Dear Ms. Hale:

We inspected your firm located at 2501 Wayne Rd., Savannah, TN, on March 6 & 7, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). Seafood HACCP information is also available through links in FDA's home page at www.fda.gov.

These deviations, most of which were previously brought to your attention in our letter dated March 28, 2001, cause your products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health. Our main concern is the failure to implement HACCP plans to control potential *Clostridium botulinum* growth or toxin formation.

The deviations were as follows:

- Failure to have and implement a written HACCP plan to control the hazard of *C. botulinum* for processed roe obtained by your firm from other processors, as required by **21 CFR 123.6(b)**.

- Failure to adequately verify that the amount of salt added to the roe will prevent the formation of *C. botulinum*. **[21 CFR 123.8(a)]**

- Failure to calibrate the thermometer used to monitor cooler temperature and the scales used for weighing roe and salt, as required by **21 CFR 123.8(a)(2)(ii)**.

- Temperature recording charts and temperature monitoring logs are not maintained as required by **21 CFR 123.6(c)(7)**. For instance, only nine weeks of temperature recording charts exist since March 22, 2001 and temperature-monitoring logs have not been completed since January 6, 2002.

- Temperature recording charts and temperature monitoring records have not been reviewed, signed and dated as required. **[21 CFR 123.8(a)(3)]**

- The verification procedures listed in your HACCP plan to control *C. botulinum* in the roe processed at your facility are not appropriate. **[21 CFR 123.6(b)(6)]** Your HACCP plan does not state how often the following verification activities will occur:

  - Calibration of scales used to weigh roe and salt
  - Calibration of thermometers
  - Finished product sampling and analysis to determine water phase salt, pH, or water activity, as appropriate
  - Accuracy checks for temperature recording chart

In addition, you do not yet have a written HACCP plan to control the hazards of pathogens and *C. botulinum* associated with vacuum-packed smoked fish processed by your firm, as required by **21 CFR 123.6(b)**. While you reported that this product is currently in development, you must implement a written HACCP plan before you distribute any product in consumer channels.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please respond in writing within fifteen (15) working days from the receipt of this letter. Your response should outline the specific steps you have taken to correct the above deficiencies in your HACCP plan and product labeling. Your reply should be addressed to the attention of Karen Gale Sego, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

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